



Overcoming Barriers to Adding Specialty to your Home Infusion Model

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I have the following financial relationships to disclose:

Ownership Interest: Rhythm Group, LLC

2. Disclosure of Off-Label and/or investigative Uses

I will not discuss off label use and/or investigational use in my presentation

Jonathan Ogurchak, PharmD, CSP

- Co-Founder & CEO – STACK
- Managing Partner – Rhythm Group
 - 10+ years in specialty pharmacy
 - Adjunct Professor: Master of Pharmacy Business Administration (MPBA) program, University of Pittsburgh
- Editorial Board: Specialty Pharmacy Times
 - Certified Specialty Pharmacist
- ACHC Certified Accreditation Consultant
 - Education Consultant - NASP



Objectives

At the conclusion of this presentation, participants will be able to:

- Describe the definition of “specialty”, it’s history with home infusion, and where it fits in the continuum of care
- List functional areas of specialty requirements, such as accreditation and reporting
- Explain supply chain and contracting limitations related to specialty product distribution

What products are considered specialty?

- Varies by manufacturer to manufacturer
- Varies from payor to payor
- General definition (1+ of the following criteria):
 - Treats chronic condition
 - Specialist-initialized
 - Requires special handling (cold-chain)
 - Costs in excess of \$670/month per patient
 - Restricted distribution
 - Biotech product
 - Injectable formulation
 - REMS Program

What is “Specialty” Pharmacy?

- 3/1/2016 – National Association of Specialty Pharmacy (NASP) Definition
 - State-licensed & accredited by third parties
 - Provide medications for patients with serious health conditions that require complex therapies
 - Provide services for patients including proper medication use, comprehensive treatment assessment, monitoring, and frequent interaction
 - Improve adherence and appropriate medication use

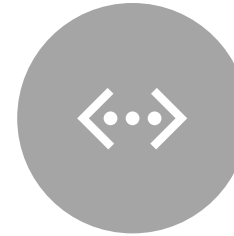
Specialty Populations

- Oncology
- HIV/AIDS
- Rheumatoid Arthritis
- Multiple Sclerosis
- Hepatitis C
- Hemophilia
- Pulmonary Hypertension
- Immune Deficiency
- Lysosomal Storage Disorders
- Other Rare/Orphan Diseases
- Note: many populations overlap with traditional Home Infusion Business!

Areas for Specialty Differentiation



ACCREDITATION



TECHNOLOGY



REPORTING
REQUIREMENTS



RESTRICTED
DISTRIBUTION



CLOSED/NARROW
NETWORK PAYERS



INVENTORY
CONTROL



Accreditation Programs

Specialty Pharmacy Focused



URAC

"Gold Standard" for Specialty Pharmacies

472 SP with full accreditation (up from 367 last year)

Focus on key measures

50 unique programs overall



ACCREDITED
SPECIALTY PHARMACY

URAC

Mandatory measures (5)

- Call Center Performance
- Dispensing Accuracy
- Distribution Accuracy
- Turnaround Time for Prescriptions
- Treatment of Chronic Hepatitis C:
Completion of Therapy



ACCREDITED
SPECIALTY PHARMACY

URAC

Exploratory measures (7)

Drug-Drug Interactions

Proportion of Days Covered (PDC)

Adherence to Long-Acting Inhaled
Bronchodilator Agents in COPD
Patients

Adherence to Non-Infused Biologic
Agents to Treat Rheumatoid Arthritis

Adherence to Non-Infused Disease-
Modifying Agents Used to Treat
Multiple Sclerosis

Fulfillment of Promise to Deliver

Primary Medication Non-Adherence
(PMN)

Consumer Experience with
Pharmacy Services



ACCREDITED
SPECIALTY PHARMACY

ACHC

CMS Deeming Authority (w/DMEPOS)

Focus on structure in relation to application of services

876 locations with full accreditation (up from 505 last year)



ACHC

Standards for Accreditation

Organization & Administration

Program/Service Operations

Fiscal Management

Human Resource Management

Provision of Care & Record
Management

Quality Outcomes / Performance
Improvement

Risk Management: Infection &
Safety Control



CPPA

Similar Standards, more wholistic

- Organizational Infrastructure
- Access to Medications
- Clinical & Patient Management Services
- Quality Improvement

99 locations fully
accredited (up from 76 last
year)



Digital Pharmacy Accreditation

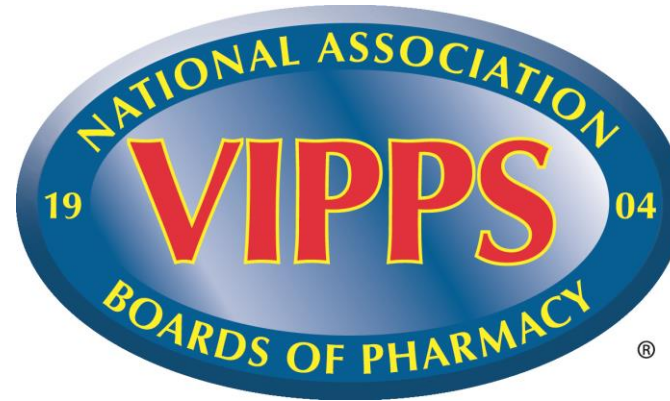
Formerly known as VIPPS

Online Presence Focused

74 locations accredited (up from 64 last year)

Recommended for "safe" purchase of prescription medications

As of 6/1/15, easier access for .pharmacy domains



Drug Distributor Accreditation

Formerly known as VAWD

Wholesaler Focused

Validate ability to safely hold and wholesale products on behalf of manufacturers

24 states recognize accreditation

661 facilities nationwide



The Joint Commission

No "Specialty Pharmacy" certification
specifically

"Home Care"

Focus on overall patient care & outcomes



The Compliance Team

Deeming Authority

Specialty Pharmacy-focused program

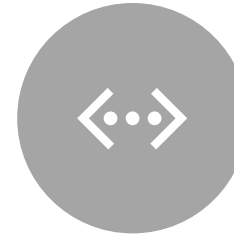
Historically DMEPOS, LTC



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Technology

Specialty Pharmacy
Focused



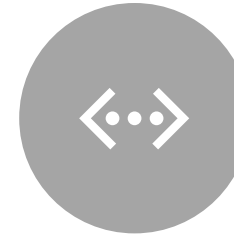
Why Technology?

- Claims Adjudication
- Referral Management
- Documentation of Patient Management / Care Programs
- Data Extraction / Aggregation
- Patient Engagement

Areas for Specialty Differentiation



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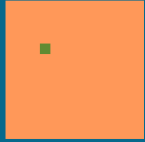
Reporting Requirements & Data

Specialty Pharmacy Focused



Why Data in Specialty?

- Visibility
 - Prescribers / habits
 - Regional distribution of lives
 - Patterns
 - Health plan acceptance / cost / benefit structure
- Outcomes / Care Management
 - What happens when...
 - What types of interventions?
 - How well did they work?
 - What types of Side Effects?
- Contractual performance



Blue: Hyperlipidemia
(102M patients)

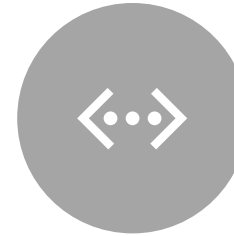
Orange: Rheumatoid Arthritis
(1.5M patients)

Green: Spinal Muscular Atrophy
(10,000 patients)

Areas for Specialty Differentiation



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RESTRICTED
DISTRIBUTION



CLOSED/NARROW
NETWORK PAYERS



INVENTORY
CONTROL



Restricted Distribution

Narrow Networks

Inventory Control



Distribution Networks

- Availability of product driven by setup of “network”
 - Open Network
 - Specialty Network
 - Limited Distribution Network
 - Exclusive Distribution Network
- Maintaining the “Patient Journey”
- Better manage cost within the system
- Contractually managed

Specialty Drug Channel Strategies

Open Channel

Limited

Exclusive

Closed/Narrow Network Payors

- Similar to inventory restriction, ability to maintain patient experience while on product
- Patient specialty utilization = investment
- Contractually managed
- Restrictions based on areas discussed thus far
- Cost control (lower reimbursement/margins)

Inventory Control

- Manufacturing Control
 - Predictive utilization
 - Shared facility
- Cost-reduction
 - Direct purchasing / wholesaler removal
- Patient Journey Maintenance

Summary

Several key areas where home infusion & specialty can overlap

Structural framework may already be in place

Business decision to determine if crosswalk of service areas right for
you



QUESTION & ANSWER



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